



## Centers for Medicare & Medicaid Services

[Document Identifier CMS-10511 and CMS-10440]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number: \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing)

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

*Contents*

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10511 Medicare Coverage of Items and Services in FDA Investigational Device

Exemption Clinical Studies--Revision of Medicare Coverage

CMS-10440 Data Collection to Support Eligibility Determinations for Insurance

Affordability Programs and Enrollment through Health Insurance

Marketplaces, Medicaid and Children's Health Insurance Program

Agencies

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### *Information Collection*

1. *Type of Information Collection Request:* Reinstatement without change; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies--Revision of Medicare Coverage; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201-405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are

met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number*: CMS-10511 (OMB control number: 0938-1250); *Frequency*: Yearly; *Affected Public*: Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents*: 116; *Total Annual Responses*: 116; *Total Annual Hours*: 232. (For policy questions regarding this collection contact Xiufen Sui at 410-786-3136.)

2. *Type of Information Collection Request*: Reinstatement without change; *Title of Information Collection*: Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies--Revision of Medicare Coverage; *Use*: Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each state a single, streamlined application form that may be used to apply for coverage through a Marketplace and for APTC/CSR, Medicaid, and CHIP (which we refer to collectively as insurance affordability programs). The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who may qualify for the programs by developing materials at appropriate literacy levels and ensuring accessibility.

45 CFR §155.405(a) provides more detail about the application that must be used by Marketplaces to determine eligibility and to collect information necessary for enrollment. Eligibility standards for the Marketplace are set forth in 45 CFR §155.305. The information will be required of each applicant upon initial application, with some subsequent information collections for the purposes of confirming accuracy of previous submissions and for changes in an applicant's circumstances. 42 CFR §435.907 and §457.330 establish the standards for state Medicaid and CHIP agencies related to the use of the application. CMS has designed a dynamic electronic application that will tailor the amount of data required from an applicant based on the

applicant's circumstances and responses to particular questions in the FFM (please note SBM implementations may vary but the essence of the data collection must adhere to the same parameters). The paper version of the application will not be tailored in the same way but will require only the data necessary to determine eligibility.

Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (i.e., Medicaid, CHIP, and APTC), and assist consumers in enrolling in a QHP if eligible.

Applicants include anyone who may be eligible for coverage through any of these programs.

*Form Number:* CMS-10440 (OMB control number: 0938-1191); *Frequency:* Annually; *Affected*

*Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of*

*Respondents:* 4,884,000; *Total Annual Responses:* 4,884,000; *Total Annual Hours:* 2,205,614.

(For policy questions regarding this collection contact Anne Pesto at 410-786-3492.)

Dated: April 1, 2022.

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**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

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